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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,279	07/08/2003	Richard Harkins	51791AUSD1	4679

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EXAMINER	
SZPERKA, MICHAEL EDWARD	
ART UNIT	PAPER NUMBER
1644	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/616,279	HARKINS ET AL.	
	Examiner	Art Unit	
	Michael Szperka	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-29,31-41 and 44-53* is/are pending in the application.

4a) Of the above claim(s) *24-29,31-34,36-41,44-46,49,52 and 53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35,47,48, 50, and 51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendments and reply received November 22, 2006 are acknowledged.

Claims 1-23, 30, 42, and 43 have been canceled.

Claim 35 has been amended.

Claims 47-53 have been added.

Claims 24-29, 31-41 and 44-53 are pending in the instant case.

Claims 24-29, 31-34, 36-41 and 44-46 stand withdrawn from consideration as being drawn to a nonelected invention. See 37 CFR 1.142(b) and MPEP § 821.03, for reasons of record set forth in the restriction requirement mailed April 1, 2005.

New claims 49, 52 and 53 are also withdrawn from consideration as methods of treating diseases in vivo are properly part of Group III of the restriction requirement mailed April 1, 2005 for the reasons set forth therein.

Claims 35, 47, 48, 50, and 51 are under examination as they read on methods of destroying a cell that expresses SEQ ID NO:2.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claim 35 stands and new claims 47, 48, 50, and 51 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 26 of copending Application No. 10/624,884 for the reasons of record set forth in the office action mailed July 5, 2005.

Briefly, the copending method discloses the use of immunoconjugates to destroy cells expressing SEQ ID NO:2. The copending immunoconjuagtes comprise specific antibodies and antibody fragments that are linked to cytotoxic agents such as ricin, the radioisotopes ^{46}Sc and ^{90}Y, and as such it would be obvious to use such immunoconjugates in the recited method.

Applicant has acknowledged this rejection, stating that "this issue is not ripe" and that "Applicants will revisit this issue at the appropriate time, i.e. when the Patent Office allows the overlapping claims in the subject application."

The rejection is maintained.

4. Claim 35 stands and new claims 47, 48, 50, and 51 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 26 of copending Application No. 10/895,183 due to anticipation of the instant invention for the reasons of record set forth in the office action mailed July 5, 2005.

Briefly, the copending method discloses the use of immunoconjugates to destroy cells expressing SEQ ID NO:2. The copending immunoconjuagtes comprise specific antibodies and antibody fragments that are linked to cytotoxic agents such as ricin, the radioisotopes ^{46}Sc and ^{90}Y, and as such it would be obvious to use such immunoconjugates in the recited method.

Applicant argues that the claims of the '183 application are limited to human antibodies, a limitation not taught in the subject application and therefore the copending claims are patentably distinct.

This argument is not convincing because human antibodies anticipate the broader genus of antibodies recited as part of the immunoconjugates of the instant

application. Note that a human antibody of a given SEQ ID number is a monoclonal antibody.

The rejection is maintained.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. The rejection of claim 35 under 35 U.S.C. 112, first paragraph, for failure to enable immunoconjugates comprising antibodies that bind epitopes 70% identical to the epitopes of amino acids 28-46 of SEQ ID NO:2, 77-91 of SEQ ID NO:2, 188-210 of SEQ ID NO:2, and 263-274 of SEQ ID NO:2, and well methods of destroying cells by administering immunoconjugates comprising the genus of therapeutic agents has been withdrawn in view of applicant's claim amendments received November 11, 2006.

Specifically, independent claim 35 has been amended to remove percent identity language and to specifically recite cytotoxic agents.

7. The rejection of claim 35 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because the claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention has been withdrawn in view of applicant's claim amendments received November 22, 206.

Specifically, these amendments remove the phrase "therapeutic agent" and replace it with "cytotoxic agent" and the specification discloses a representative numbers of cytotoxic agent species to demonstrate that applicant had possession of the recited genus at the time the application was filed.

Applicant's claim amendments received November 22, 206 have also raised the following new issues:

8. Claim 51 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicant has added dependent claim 51 which recites a large number of radioisotopes. Applicant indicates that support for these species can be located in the paragraph spanning pages 30 and 31 of the instant specification. Examination of the specification fails to find disclosure of many recited species such as ^{47}Sc, ^{48}Sc, ^{72}Ga, 73Ga, ^{67}Cu, ^{109}Pd, ^{149}Pm, ^{153}Sm, ^{166}Ho, ^{177}Lu, ^{186}Re, ^{188}Re, ^{211}At, ^{211}Bi, ^{212}Bi, ^{213}Bi, and ^{214}Bi. Further, some species such as ^{11}Ag are impossible. Radioisotopes are identified by their atomic mass, such as ^{46}Sc. The atomic number for scandium is 21 and as such ^{46}Sc comprises 25 neutrons in addition to the 21 protons that identify the element as scandium (see Gillespie et al.). The atomic number for silver (Ag) is 47, and as such it is not possible to have an isotope of silver that comprises only 11 nucleons (ibid). In response to this rejection, applicant should either point out where appropriate support can be located in the specification as filed or amend the claims accordingly.

9. No claim is allowable.

10. Applicant's amendment necessitated the new ground of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael Szperka, Ph.D.
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Technology Center 1600
January 25, 2007

1/30/07
G.R. EWOLDT, PH.D.
PRIMARY EXAMINER